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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,159	NYBERG ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *14-21 and 31-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 22-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/25/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The remarks filed 18 April 2007 have been entered. Claims 1 – 65 are pending.

Election/Restrictions

2. Applicant's election without traverse of Group I (claims 1 – 13 and 22 – 30, to the extent that the claims encompass administration of proteins) in the reply filed on 18 April 2007 is acknowledged.

3. Claims 14 – 21 and 31 – 65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 18 April 2007.

4. Claims 1 – 13 and 22 – 30 are under examination.

Priority

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) and 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application Nos. 60/387390 and 0201783-8 (Sweden), fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The U.S. provisional document and the Swedish foreign priority document each fail to disclose the sequence of SEQ ID NO:4, which is recited in claims 22 and 24 – 30 and is encompassed by claim 23, which depends from claim 22. Claims 22 – 30 each encompass administration of the protein of SEQ ID NO:4, which is not disclosed in either the U.S provisional application or the Swedish priority document. Methods of administering SEQ ID NO:2 for treatment of disease are however disclosed (it is noted that in the priority documents there is a single sequence, SEQ ID NO:1,

which is identical to instant SEQ ID NO:2). Therefore, for the purposes of applying prior art, the effective filing date of claims 1 – 13 is 11 June 2002 and the effective filing date of claims 22 – 30 is 11 June 2003, the date that PCT/EP03/06207 was filed.

Should applicant disagree with the examiner's factual determination above, applicant should provide evidence that either of the earlier-filed applications in fact provides enablement and written description of the methods of administering instant SEQ ID NO:4 in a manner consistent with the requirements of the first paragraph of 35 U.S.C. 112. This could be accomplished, for example, by pointing out the page and line numbers where SEQ ID NO:4 appears and where the methods of administering this protein appear.

6. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

7. Claims 10, 22, and 27 are objected to because of the following informalities: they contain improper grammar and awkward phrases.

Claims 10 recites "compound has an identity corresponding to" at line 2. To reflect more conventional claim language, it is recommended that applicant amend the claim to read "compound is at least about 75%... 99% identical to SEQ ID NO:2".

Claim 22 recites "treatment of overweight" which is grammatically incorrect. To reflect more conventional claim language, it is recommended that applicant amend the claim to read "A method for prophylaxis or treatment of obesity...".

Claims 27 recites "compound has an identity corresponding to" at line 2. To reflect more conventional claim language, it is recommended that applicant amend the claim to read "compound is at least about 75%... 99% identical to SEQ ID NO:2 or SEQ ID NO:4."

Appropriate correction is recommended.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6, 11 – 12, and 28 – 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 4 and 6 the phrase "such as" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The term "similar to" in claims 11 and 28 and the term "a similarity corresponding to" in claims 12 and 29 are relative terms which render the claims indefinite. The terms "similar to" and "a similarity corresponding to" are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree of similarity, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Additionally, it is unclear whether "similarity corresponding to" refers to a similar structure, as implied by claims 12 and 29, or similar function, encompassed by the base claims (1 and 22 respectively).

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 – 13 and 22 – 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of the proteins of SEQ ID NO:2 and SEQ ID NO:4, does not reasonably provide enablement for treatment and prophylaxis of diseases and conditions as broadly claimed or for administration of compounds of undefined structure with activities similar to SEQ ID NO:2 or 4 that are revealed when said compounds are tested in assays, or for administration of analogues or fragments of SEQ ID NO:2 or 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of

experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988).

In the instant case, the nature of the invention is complex. The claims are drawn to methods for prophylaxis or treatment of any disease either characterized by or caused by abnormal loss of cells (claim 1), which comprise administering to a subject a composition comprising a compound that has cell-proliferating activity at least 50% of that of the protein of SEQ ID NO:2. The breadth of the claims is greater than what is actually disclosed or enabled in the specification for several reasons.

1) Claims 1 – 8, 11 – 13, 22 – 25, and 28 – 30 are drawn to administration of compounds whose structure is not disclosed but that may be discovered in a screening assay to be performed by the skilled artisan. Independent claims 1 and 22 do not require that the compound to be administered have any particular structure, only that it have an activity at least 50% as great as that of SEQ ID NO:2 (claims 1 and 22) or SEQ ID NO:4 (claim 22). The specification describes screening assays which might be able to find such a compound (see for example page 2 line 31 – page 3 line 2) but does not disclose the full scope of structures of the compounds which are in compositions to be administered in accordance with claims 1 and 22.

The screening assay described is long and involved, as it requires testing compounds in an assay and determining whether they modulate proliferation (claim 1) or administering compounds within rats' brains, waiting for a recovery period, and monitoring weight changes (claim 22). The claims are akin to product-by-process claims, but they do not actually recite steps that will put the skilled artisan in possession of the composition to be administered to a subject. Rather, the compounds to be administered in the claimed methods must first be manufactured and then identified in the screening assays. The assays may or may not identify compounds that could be effective in treating or preventing at least one of the diseases encompassed by the claims, but the assays do not allow the artisan to make the compounds so screened. Which compounds will be identified by the screening assay is entirely dependent upon the compounds that are to be screened.

In order to make the compounds which are in the compositions to be administered in claims 1 and 22 (and dependent claims 2 – 8, 11 – 13, 23 – 25, and 28 – 30), the artisan would have to have some idea of what their structures are. However, the claims do not specify any structure whatsoever. Claims 1 – 8 and 22 – 25 are drawn to methods wherein the compositions to be administered are defined in terms of their function only. Claims 11 – 13 and

28 – 30 are so broad that they allow for any possible structure (see more on this point below). Thus the skilled artisan would have to guess how to make the compounds required to be administered in the claimed methods. The breadth of the claims includes any compound, with any size and any structure, so long as it either has the requisite proliferating (claim 1) or weight-modulating activity (claim 22). This breadth includes for example small organic molecules, antibodies, nucleic acids, and polypeptides, none of which share common structural elements with each other. While the specification discloses the proteins of SEQ ID NO:2 and SEQ ID NO:4, it does not disclose to the artisan how to make the full genus of compounds that might be found in the screening assays, as what is identified in the screening assay is entirely dependent upon what chemical compounds are screened. Furthermore the art recognizes that a molecule's function is dependent upon its structure. For example, Alberts et al. (1994. Molecular Biology of the Cell pp. 129 – 130) teaches that protein function is determined by shape. Of course the same logic applies that have activities related to SEQ ID NO:2 or 4, as the screening assays themselves depend upon interactions with proteins. The claims are not limited to administering compositions comprising compounds with structural homology to SEQ ID NO:2 or 4 (with the exception of claims 9 – 10 and 27 – 28), but rather to compositions of undisclosed structure.

The specification offers no working examples of compounds other than the proteins of SEQ ID NO:2 and 4 which fall within the scope of the claims. There is no guidance in the specification as to what constitutes the structure of the compounds administered in the claimed methods. The very broad nature of the claims means that the skilled artisan would have to determine what that structure is. Because the specification does not disclose the chemical composition of the structures to be administered in the methods now claimed, the skilled artisan would be unable to make the full scope of the claimed invention, or even a reasonable number of members representative of the genus as a whole. The artisan would have to discover the structures of these starting materials on his or her own. Given the very broad nature of the claims, coupled with the lack of sufficient guidance in the specification, the degree of experimentation required on the part of the skilled artisan would be undue.

2) Claims 1 and 22, both of which are independent claims, are drawn to methods for prophylaxis or treatment of various diseases. Prophylaxis is not explicitly defined in the specification, but the broadest reasonable interpretation of the term includes prevention of disease. Treatment of disease is explicitly defined in the specification (p. 6 lines 10 – 17) as

including prevention of the disease. The art recognizes that prevention of neurological diseases is essentially not possible. For example, Vickers teaches that Alzheimer's disease (encompassed by claims 1 – 13 and explicitly recited in claims 4 and 6) develops in advanced age and there are currently no treatments available to prevent this disease (Vickers, 2002. Drugs Aging 19:487-494, see especially p. 487 first paragraph). Complete treatment of this disease is also recognized to be impossible; see for example Anderson (U.S. Patent 5,589,154), particularly column 3 lines 56 – 60, where the reference teaches that complete cures are impossible although certain therapies exist which ameliorate specific symptoms of the disease. Similarly "overweight", which is encompassed by claims 22 – 30, cannot be prevented. This term is not explicitly defined in the specification and is so broad that it reasonably includes weight gain of any sort. The skilled artisan would immediately realize that weight gain is a normal part of growth and development, and that weight can change within a week or even within a single day. The specification fails to demonstrate prevention of "overweight" as recited in claim 22. There is no demonstration of prevention of diseases in the specification. The art generally recognizes that prevention is impossible. In the absence of either working examples or guidance in the specification as to how to overcome the impossible nature of prevention, claims to methods of prophylaxis could not be practiced by the skilled artisan in the absence of undue experimentation. As applicant has quite clearly defined "treatment" to include prevention, claims to "treatment" are not considered enabled for the same reason.

3) Claims 1 – 13 encompass methods of treating any disease characterized by "abnormal cell loss" (claim 1); dependent claims recite specific diseases (claims 4 and 6). Even given a more narrow definition of treatment (such as that set forth at p. 6 line 15-16 of the specification, arresting development or causing regression of a disease), the specification is not enabling for treatment of all "conditions caused or characterized by abnormal loss of cells" as recited in claim 1 and is not reasonably enabling for treating any of the diseases recited in claims 4 and 6. The specification provides evidence that administration of porcine GIP (obtained from Sigma, the protein differs by two amino acids from SEQ ID NO:4 and three amino acids from SEQ ID NO:2; see enclosed printout from Sigma website) increases proliferation of hippocampal progenitor cells (see p. 27). It is not reasonable that either SEQ ID NO:2 or SEQ ID NO:4 would be effective in treating all "conditions caused or characterized by abnormal loss of cells" as recited in claim 1 and encompassed by claims 2 – 3, 5, and 7 – 13. Conditions caused or characterized by abnormal loss of cells include cancer, which is at least

characterized, and perhaps even caused by, an abnormal decrease in the rate of cell death and corresponding over-proliferation of cells. Cancer is an excessive growth of cells, and cell lines derived from tumors are referred to as "immortal". That is, they do not die, so the rate of loss of cells is abnormally low. Adding a compound that increases proliferation, such as that of SEQ ID NO:2 or 4, would be expected to exacerbate, not treat, cancer. As the only working examples set forth in the specification are drawn to methods of *increasing* proliferation, it is not reasonable that the same starting materials would be expected to decrease proliferation. In the absence of sufficient guidance as to how to change a proliferation-inducing molecule into a proliferation-inhibiting molecule, the skilled artisan would have to resort to undue experimentation in order to accomplish this.

Additionally, while the specification is enabling for slowing increase in weight gain by administration of porcine GIP (see p. 33 and Figure 5), the specification is not reasonably enabling for treatment of any of the conditions encompassed by claims 1 – 3, 5, and 7 – 13 or recited in claims 4 and 6. The specification discloses that porcine GIP proteins (which are structurally related to SEQ ID NO:2 and 4) increase brain progenitor cell proliferation. This assay is not an art-accepted model for any disease or condition. It is not indicative of treatment of Alzheimer's disease, recited in claims 4 and 6. Realistic animal models of Alzheimer's disease do exist. These include, for example, the PDAPP transgenic mouse which shows behavioral symptoms and pathophysiology not unlike what is seen in humans. See Janus (2000. Nature 408:979 – 982) for a description of these mice and a treatment which both ameliorates behavioral symptoms and reduces the presence of plaques. Increased brain progenitor cell proliferation is not indicative of treatment of skin disease or diabetes (recited in claim 4), as these are caused by viruses (e.g. varicella which causes the skin disease known as chicken pox) or loss pancreatic cells respectively. Increased brain progenitor cell proliferation is not indicative of improving learning and memory; see for example Merrill (2003. The Journal of Comparative Neurology 459:201-207), who teaches that there is no correlation between spatial learning ability and birth of hippocampal cells in rats. While the specification discloses that a Morris Water Maze test was performed (p. 32), no results are provided and the skilled artisan would expect that a change in cell proliferation would be unrelated to a change in learning, given the findings of Merrill.

4) Claims 13 and 30 encompass administration of analogues and fragments of certain protein sequences. There is no requirement that the analogues or fragments have any

particular activity. There is no requirement that the fragments have any particular structure. The breadth of "fragments" allows for as little as a single amino acid to be present; clearly as protein function is dependent upon the structure (see Alberts, cited above), such fragments would not be expected to have the same activity as the full-length proteins. With respect to "analogue", the term is defined at p. 5 lines 4 – 9 of the specification and allows for unlimited number of possible additions, substitutions, or deletions of amino acids (note use of "one or more" in describing the changes to the sequence). Thus claims 13 and 30 read on an unlimited number of possible proteins of any structure and any function. It is not reasonable to expect that all proteins would be effective in treating the diseases encompassed by claims 1, 13, 22, and 30 for example, especially in light of the teachings of Alberts with respect to the correlation between structure and function. Changing amino acids would be expected to change protein function.

The specification provides no examples of administering products commensurate in scope with claims 1 and 22, drawn to products of undefined structure, other than the proteins of SEQ ID NOs:2 and 4. The specification provides no examples of treating any disease caused or characterized by abnormal cell proliferation. While there is evidence that a structurally similar protein (porcine GIP) slows weight gain, prevention of obesity and overweight as encompassed by claim 22 is not reasonably possible. The specification fails to show evidence that all analogues and fragments of SEQ ID NOs:2 and 4, encompassed by claims 13 and 30, would be therapeutic or prophylactic as claimed. The state of the art indicates that changing protein sequences would result in changed activity. There is not sufficient guidance in the specification to allow the skilled artisan to overcome the barriers to enablement set forth in the preceding pages. Given the lack of working examples and adequate guidance in the specification, the skilled artisan would have to resort to a very large degree of experimentation to practice the claimed methods over their full scope. Such a large degree of experimentation would clearly be undue.

10. Claims 1 – 13, and 22 – 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1 – 8, 11 – 13, 22 – 25, and 28 – 30 are drawn to methods of administering a composition comprising a compound that can be identified in a screening assay. The compounds to be administered in these methods have not been described. Independent claims 1 and 22 describe a screening assays that could be used to identify compounds with activities similar to SEQ ID NO:2 or 4. No structurally defined compounds are listed in these claims. Because no structure is listed in the claims, the skilled artisan could not determine what structures are encompassed by the claims. Rather than describing to the public the actual starting materials for the claimed methods, the claims and specification describe to the public a plan for obtaining it. Of course what is actually identified in the screening assay depends upon what compounds are screened. If a library of antibodies is screened, the assay might identify some antibodies. If a library of small organic molecules is screened, the assay might identify some small organic molecules. However, knowing how to do the steps of the assay does not describe the starting materials required for the methods invention now claimed.

The instant disclosure of a screening assay does not adequately support the scope of the claimed genus, which encompasses methods of administering a substantial variety of compounds of unlimited structure. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co,* 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

Here, applicant has not described a reasonable number of members of the genus of compounds to be administered in the claimed methods, but rather has presented the public with an idea of how to perform an assay that might identify some agents that could be used in the

methods. Of course, depending on what agents are used in the screening assay, it may well identify none.

The instant claims are often referred to as "reach-through" claims, where an applicant attempts to obtain patent protection on an invention not yet discovered. The Court of Appeals for the Federal Circuit addressed claims of this sort in great detail in *University of Rochester v. G.D. Searle and Co.* (69 USPQ 2nd 1886, CAFC 2004). In *Rochester*, the Federal Circuit upheld the district court's ruling that patent claims which recited administration of compounds not disclosed, but rather to be identified in a screening assay, were invalid on their face. Here, the situation is analogous to that in *Rochester*. Since the specification does not disclose to the public the structures to be administered in the claimed methods, it does not meet the written description requirement of 35 USC § 112, first paragraph.

Claims 10, 12, 27, and 29 encompass methods of administering compounds of varying degrees of identity or similarity to disclosed protein sequences. The variants have not been described in the specification, nor have the proteins which are "similar" to the disclosed sequences. Claims 13 and 22 encompass methods of administering proteins of defined sequence as well as "analogues or fragments thereof." The analogues and fragments have not been described in the specification. The term "analogues is defined very broadly in the specification to include proteins with any number of possible insertions deletions, or substitutions; no particular structural or functional elements are required. The skilled artisan cannot envision which fragments, variants, or analogues are encompassed by the claims. The specification fails to describe to the artisan which structures are common to all members of the compounds to be administered in the claimed methods. The specification does not disclose whether those compounds which have "an identity corresponding to at least about 75%" to a disclosed sequence are missing the first 25%, the last 25%, or 25% of the amino acids in the middle. The specification fails to provide evidence of possession of the broad group of genera and subgenera of compounds recited in the claims. Thus the specification cannot provide evidence of possession of the methods now claimed.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 13 and 22 – 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Bollag (2001. Molecular and Cellular Endocrinology 177:35 – 41, cited on IDS filed 25 January 2006).

Bollag teaches methods of administering human GIP to animal subjects. The specification discloses that human GIP has the sequence of SEQ ID NO:2 (see p. 2 final paragraph). Absent evidence to the contrary, the product disclosed in the Bollag reference appears to be identical to that identified by applicant as SEQ ID NO:2 and therefore is on point to all claims under examination. In both cases, they are identified as human GIP (see Bollag, p. 37 section 7.3 and specification p. 2 final paragraph). The compound necessarily has the same activity as SEQ ID NO:2 and thus is within the scope of claims 1 and 22 as well as claims 8 and 25 (encompassing administering compounds with activity at least about 100% of SEQ ID NO:2), as well as claims 13 and 30, which encompass administration of the protein of SEQ ID NO:2 . Bollag teaches administration of the compound, which is the sole step required in claims 1 – 13 and 22 – 30. See p. 37 second column section 7.3 for description of the administration of GIP to rats. Note that claims 1 – 13 do not require that the subject who receives the compound have any particular disease or condition; the only requirement is that the compound be administered. The method of claims 1 – 13 includes prophylaxis and prevention of disease and clearly includes administering the compounds to asymptomatic patients (see the definition of treatment set forth on p. 6 of the specification). As the prior art reference clearly teaches administration of the compound to asymptomatic patients, which is the sole step required for claims 1 – 13, it anticipates the claimed invention.

Claims 2 – 3 and 5 recite certain types of abnormal cell loss. However since the claims encompass prevention of the disease and allow for administration of the compound to asymptomatic persons, the reference by Bollag anticipates these claims.

Bollag teaches that animals which receive the drug gain weight at the same rate as those animals that do not receive the drug (p. 39 second column first complete paragraph). As the animals gain weight no faster than controls, the method taught by Bollag is reasonably one of preventing obesity(the animals did not become obese) and therefore is on point to claims 22 – 30. Note that claim 23 requires that the composition "further comprises a carrier allowing the transport of the compound across the blood brain barrier". Bollag's GIP compound was

delivered in the carrier physiological saline, which allows for transport across this barrier (BBB). No structure is recited in claim 23, and the claim does not require that the amount of transport across the BBB be increased in the presence of the carrier. The only requirement is that the carrier "allow" (i.e. not prevent) the transport to occur. As the entire BBB is bathed in solutions comprising saline, it is reasonable that saline allows transport to occur.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DK

Daniel E. Kolker, Ph.D.
June 18, 2007

Patent Examiner